

Appl. No. 09/784,665
Amdt. dated November 9, 2004
Reply to Office Action of August 11, 2004

REMARKS

Applicants have carefully reviewed the Office Action mailed on August 11, 2004. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. Claims 1-21 remain pending.

As a preliminary matter, Applicants bring to the Examiner's attention that formal drawings were submitted on May 22, 2001, but there has been no indication of approval of the drawings by the Examiner or the Official Draftsman. Applicants request that the Examiner/Official Draftsman indicate approval or non-approval of the formal drawings with the next PTO communication.

Claims 1-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over McIntyre et al. in U.S. Patent No. 5,334,153 in view of Gabel et al. in U.S. Patent No. 4,759,751. The Examiner indicated that McIntyre et al. disclose a catheter as claimed except for a pierceable seal. The Examiner further indicated that Gabel et al. disclose a pierceable seal and that it would be obvious to combine the teachings of Gabel et al. with McIntyre et al. to arrive at the claimed invention. We respectfully disagree.

M.P.E.P. §2143 states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met: there must be some motivation to combine the references, there must be a reasonable expectation of success, and all the claim limitations must be taught or suggested. Applicants respectfully submit that a *prima facie* case of obviousness has not been properly established at least for the reason that all the claim limitations are not taught and, in the alternative, because there is no reasonable expectation of success.

Regarding claims 1-16, independent claims 1 and 9 each recite a pierceable seal. It should be noted that the claimed pierceable seal also includes additional structure that distinguishes it from the art. More particularly, claims 1 and 9 both recite that the seal is (a) "releasably attached to the first port," and that the seal is (b) attached in such a manner "so as to substantially prevent the passage of air into the first lumen." First of all, it does not appear that the gasket, which the Examiner has attempted to equate with the claimed seal, is releasably attached to the first port. McIntyre et al. is silent as to this point but the drawings indicate that gasket 26 is an integral part of housing 21. McIntyre et al. at Figure 4. Therefore, it does not appear reasonable to suggest that the McIntyre et al. gasket could be releasable.

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Moreover, the gasket in McIntyre et al. cannot prevent the passage of air into the first lumen because, as Figure 4 clearly shows, side leg 22 independently provides an opening to the lumen. McIntyre et al. attempts to address this defect by noting that "optionally" a stopcock or three-way valve can be attached to the side leg. Even the addition of the stopcock fails to cure the deficiencies of McIntyre et al. because the gasket, even if interpreted broadly enough to be seen as "sealing", is still not releasable.

Combining Gabel et al. with McIntyre et al. fails to address these issues. Gabel et al., at column 4, lines 45-48, state:

[s]o compatibility exists between catheter tube 12 and air purging member 22, distal end 20 of the catheter tube should be penetrable or pierceable by cannula point 28.

It is not conceivable that the plug in Gabel et al. could in any way be releasably attached to a first port. If the plug were to release from the distal end, the distal end would be opened, thereby causing inflation fluid being passed through the catheter lumen to immediately leak out of the distal end. This would completely undermine the purpose of the catheter's distal end and render the catheter useless. Moreover, the pierceable distal end cannot substantially prevent the passage of air into the first lumen because, as stated by Gabel et al., the proximal end of the lumen is open. Gabel et al. at column 3, lines 62-64.

If the forgoing is not persuasive, it can be readily appreciated that if the plug in Gabel et al. were to be substituted for the gasket in McIntyre et al., the resultant device would have no reasonable expectation for success. This is because if the plug in Gabel et al. were used in place of the gasket in McIntyre et al., it would not be possible for the inner tubular member to pass through the plug in the manner described in McIntyre et al. Thus, such a combination would undermine the purpose of the gasket and render the McIntyre et al. invention useless. Clearly, these remarks indicate that combining the cited references would have no reasonable expectation of success. If it was obvious to use the teaching of Gabel et al., McIntyre et al. would have placed a releasable, pierceable seal at side leg 22 instead of a stopcock. Such a combination can only be derived by viewing Applicants' claimed invention and then using reconstructive hindsight to apply it to the cited references.

In light of the above remarks, at least two of the requirements for a *prima facie* case of obviousness are not met. As such, claims 1 and 9, as well as claims 2-8 and 10-15 depending

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therefrom, respectively, are believed to be patentable over the combination of McIntyre et al. and Gabel et al. Applicants respectfully submit that these remarks overcome the rejection.

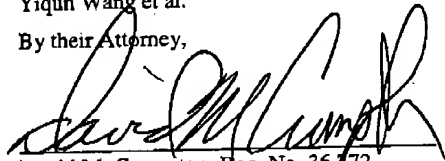
Regarding claims 16-21, claim 16 recites the steps of providing a sealing device that is detachably connectable to the first port and connecting the sealing device to the first port. As indicated by the Examiner, McIntyre et al. fail to disclose these limitations. Gabel et al. fail to correct this deficiency. As described above, neither McIntyre et al. nor Gabel et al. provide adequate teaching of these steps because the disclosed gasket and plug cannot be releasable and because they cannot seal the inflation lumen. Because each and every claim limitation is not taught or disclosed by the combination of McIntyre et al. and Gabel et al., a *prima facie* case of obviousness is not properly established. Accordingly, Applicants respectfully submit that these remarks overcome the rejection of claim 16 as well as the rejection of claims 17-21 depending therefrom.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Yiqun Wang et al.

By their Attorney,



David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

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